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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,692	12/11/2003	Philip Stashenko	25669-003	4324

7590 07/09/2007

Mintz, Levin, Cohn, Ferris,
Glovsky and Popeo, P.C.
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EXAMINER	
CHANDRA, GYAN	

ART UNIT	PAPER NUMBER
1646	

MAIL DATE	DELIVERY MODE
07/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/734,692	STASHENKO ET AL.	
	Examiner	Art Unit	
	Gyan Chandra	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 25-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 25-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/11/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Re: Stashenko et al.

Date of Priority: 12/11/2002 (60/432,700)

Election/Restrictions

Applicant's election without traverse of Group I, (claims 1,3, and 13-16) in the reply filed on 8/15/2006 is acknowledged.

Applicants' filing of the preliminary amendments on 4/18/2007 in response to Notice of compliance is acknowledged.

Status of Application, Amendments, And/Or Claims

The cancellation of claims 2-24 and the addition of new claims 25-33 have been made of record.

Claims 1 and 25-33 are pending and under examination.

Information Disclosure Statement

The Information Disclosure Statement filed on 03/11/2004 has been considered.

Applicant's Response Regarding SEQ ID NO: 50

In response to the Election/Restriction, Applicants amend claim 1 to introduce a polynucleotide sequence of SEQ ID NO: 50. Applicants state (see page 4 of Response filed on 8/15/2000) that the polynucleotide sequence of SEQ ID NO: 50 is identical to the nucleic acid sequence of gene "C80638" which is publicly available as Genbank Accession No. AV251613, and that the amendment of claim 1 to recite SEQ ID NO: 50 does not introduce any new matter. Thus, applicants' statement meets the 37CFR 157(f) requirement. See also In re Hawkins, 486 F.2d

569, 179 USPQ 157 (CCPA 1973); In re Hawkins, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); In re Hawkins, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

Claim Objections

The Examiner suggests the syntax of claim 1 can be improved by amending the claim to delete the text of complete nucleic acid sequence of OC14 and reciting "A method of inhibiting osteoclast-mediated bone resorption, comprising inhibiting activity of a gene product encoded by an osteoclast associated gene OC14 comprising a nucleotide sequence of SEQ ID NO: 50."

Claim Rejections - 35 USC § 112-written description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, and 25-33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The written description in this case only sets forth an antibody to inhibit OC14 (OCL-1E7) as taught by Choi (US Pub. No. 2003/0186297) to inhibit osteoclast resorption, and therefore the written description is not commensurate in scope with any compound which is selected from the group consisting of any fusion protein, any

polypeptide, any peptidomimetic, any antisense polynucleotide, any prodrug, any antibody, any small molecule inhibitor or any ribozyme.

The claims broadly encompass any compound that inhibits osteoclast-mediated bone resorption comprising inhibiting OC14 polypeptide. However, the claims do not require that a compound possess any particular feature that inhibits OC14 gene encoded polypeptide.

The specification on pg.13, discloses that RANKL treated RAW 264.7 macrophage cells or M-CSF in combination with RANKL treated mouse bone marrow macrophage differentiate to osteoclast like cells. The specification on page 49, discloses that osteoclast cells have differential expression of a number of genes as compared to non-osteoclast cells and that the OC14 gene is activated upon RANKL treatment. Choi teaches that a compound that binds a polypeptide OCL-1E7 (OC14), such as an antibody can be used to modulate osteoclast function [0046 and 0049].

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. Some of the factual considerations that are weighed when determining a written description include the level of skill and knowledge in the art, the disclosure of complete or partial structures, the disclosure of physical and or chemical properties, adequate disclosure of the functional characteristics, the correlation between structure and function, and disclosure of methods of making.

In the instant case, the specification (on page 49) only adequately discloses that the RANKL treated osteoclast-like macrophage cells or M-CSF and RANKL treated

mouse bone marrow macrophage have **higher OC14 gene levels.** The specification does not describe any compound including any fusion protein, any polypeptide, any peptidomimetic, any antisense polynucleotide, any prodrug, any antibody, any small molecule inhibitor or any ribozyme that inhibits a polypeptide encoded by OC 14 that may result in the inhibition of bone resorption. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed.

Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Vas-Cath Inc. V. Mahurka, 19 USPQ2d 1111, states that applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention, for purposes of the written description inquiry, is *whatever is now claimed* (see page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (see Vas-Cath at page 1116).

A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. Regents of the University of California v. Eli Lilly & Co., 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In Regents of the University of California v. Eli Lilly (43 USPQ2d 1398-1412), the court held that a generic

statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that, while applicants are not required to disclose every species encompassed by a genus, the description of the genus is achieved by the recitation of a representative number of species falling within the scope of the claimed genus. At section B (1), the court states an adequate written description of a DNA ... requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention.

As discussed above, the skilled artisan cannot envision the detailed genus of "compounds including any fusion protein, any polypeptide, any peptidomimetic, any antisense polynucleotide, any prodrug, any antibody, any small molecule inhibitor or any ribozyme" that would inhibit osteoclast resorption comprising inhibiting the activity of OC14 polypeptide and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of making a mutation. The compound itself is required. See Fiers v.Revel, 25USPQ2d 1601 at 1606 (CAFC 1993) and Amgen v.Baird, 30 Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 148 at 1483. In Fiddes, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class.

Therefore, only an antibody that specifically binds to OC14, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph.

Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, and 25-26 are rejected under 35 U.S.C. 102(e) as being anticipated by Choi, Y. (US Pub. No. 2003/0186297 published on 10/2/2003, which claims benefit of US Application No. 60/368,638, and has support for the claimed invention).

Claims 1, and 25-26 are drawn to a method of inhibiting osteoclast mediated bone resorption comprising inhibiting activity of a gene product encoded by osteoclast associated gene OC14 of SEQ ID NO: 50, wherein said activity of a gene product encoded by OC14 is inhibited by administering a compound that inhibits the activity of said gene product, and wherein said compound is selected from the group consisting of a fusion protein, a polypeptide, a peptidomimetic, an antisense polypeptide, a prodrug, an antibody, a small molecule inhibitor or a ribozyme.

Choi teaches that RAW264.7 cells are differentiated into osteoclast cells by treatment with TNF-related activation induced cytokine and that a polynucleotide of

SEQ ID NO: 1 (OCL-1E7) is expressed in the differentiated osteoclast cells [0022]. The nucleotides from 1299-1996 of polynucleotide of SEQ ID NO: 1 are 100% identical to the nucleotides 1-668 of the SEQ ID NO: 50 of the instantly claimed invention (see- the sequence alignment). The nucleotide position 49 in the instant invention is a "n" which can be any nucleotide, which is a "T" in the SEQ ID NO: 1 of US Pub. No. 2003/0186297. Further, Choi teaches that the Na-H exchanger domain that comprises aa residues 176-503 in OCL-1E7 is a regulator of bone resorption [0019 and 0025]. Choi contemplates using an agent which modulates expression of OCL-1E7 and an activity of the polypeptide encoded by OCL-1E7 gene to modulate the function of osteoclasts [0025]. Choi teaches making antibodies against said polypeptide and using an antibody for modulating osteoclast function [0046 and 0049]. Therefore, the prior art of record explicitly or implicitly anticipates the instantly claimed invention.

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RESULT 1
US-10-368-087-1
; Sequence 1, Application US/10368087
; Publication No. US20030186297A1
; GENERAL INFORMATION:
;  APPLICANT: Choi, Yongwon
;  TITLE OF INVENTION: OSTEOCLAST SPECIFIC GENES AND PROTEINS AND USES THEREOF
;  FILE REFERENCE: PENN-0843
;  CURRENT APPLICATION NUMBER: US/10/368,087
;  CURRENT FILING DATE:  2003-02-14
;  PRIOR APPLICATION NUMBER: US 60/368,638
;  PRIOR FILING DATE: 2002-03-28
;  NUMBER OF SEQ ID NOS: 16
;  SOFTWARE: PatentIn version 3.1
; SEQ ID NO 1
;   LENGTH: 1987
;   TYPE: DNA
;   ORGANISM: Mus musculus
US-10-368-087-1

  Query Match             100.0%;  Score 667;  DB 7;  Length 1987;
  Best Local Similarity   99.9%;  Pred. No. 5e-210;
  Matches  667;  Conservative    0;  Mismatches    1;  Indels    0;  Gaps    0;

Qy          1 TGGAGCAGAGGTTTCCATTGTGTCTCTCAGAGCAGAAACGGTTGGCCTNTGTGTTGCAAC 60
              ||||||||||||||||||||||||||||||||||||||||||||||| ||||||||||
Db       1299 TGGAGCAGAGGTTTCCATTGTGTCTCTCAGAGCAGAAACGGTTGGCCTTTGTGTTGCAAC 1358

Qy         61 CCTCAGCATCGCAGTGCTTATACGAATTCTGACTACATTCCTGATGGTGTGTTTCGCTGG 120
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       1359 CCTCAGCATCGCAGTGCTTATACGAATTCTGACTACATTCCTGATGGTGTGTTTCGCTGG 1418

Qy        121 CTTTAACATAAAGGAAAAGATATTTATTTCTTTTGCCTGGCTTCCAAAGGCCACGGTCCA 180
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       1419 CTTTAACATAAAGGAAAAGATATTTATTTCTTTTGCCTGGCTTCCAAAGGCCACGGTCCA 1478

Qy        181 GGCTGCCATTGGCTCTGTGGCTCTGGACACGGCAAGATCCCACGGAGAGAAGCAGCTGGA 240
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       1479 GGCTGCCATTGGCTCTGTGGCTCTGGACACGGCAAGATCCCACGGAGAGAAGCAGCTGGA 1538

Qy        241 AGACTATGGGATGGATGTGCTGACGGTGGCATTTTTGGCCATCCTCATTACAGCACCAAT 300
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       1539 AGACTATGGGATGGATGTGCTGACGGTGGCATTTTTGGCCATCCTCATTACAGCACCAAT 1598

Qy        301 TGGAAGCCTACTGATTGGTTTGCTGGGTCCCAGGGTTCTTCAGAAATCTGAACATCGAAC 360
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       1599 TGGAAGCCTACTGATTGGTTTGCTGGGTCCCAGGGTTCTTCAGAAATCTGAACATCGAAC 1658

Qy        361 CGAAGAGGAGGTTCAAGGAGAGACTTCTGCACACATTCAGAGGAAGCCTGAGGATTCCAT 420
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       1659 CGAAGAGGAGGTTCAAGGAGAGACTTCTGCACACATTCAGAGGAAGCCTGAGGATTCCAT 1718

Qy        421 TACGGAAGCCTGATGGACCATGTTTACCATCCCAACCCAAAGGTTTTGGCCCTCCAACAA 480
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       1719 TACGGAAGCCTGATGGACCATGTTTACCATCCCAACCCAAAGGTTTTGGCCCTCCAACAA 1778

Qy        481 CCGGGACAACTTTACTTCCCTTTGACTCAGAAGAAAACTTCCCGTGGAATTTCATAAGCA 540
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       1779 CCGGGACAACTTTACTTCCCTTTGACTCAGAAGAAAACTTCCCGTGGAATTTCATAAGCA 1838

Qy        541 AACAAATTAGAAAGCTTTACGCTGCTAACAGTACCTCAGGTGTTTACTTCCTCAGAAAGA 600
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       1839 AACAAATTAGAAAGCTTTACGCTGCTAACAGTACCTCAGGTGTTTACTTCCTCAGAAAGA 1898

Qy        601 CCGGAGGACAGGTTACTTCAGAAAGTGAGAGAAAGTAATTTGGACAAATAAAACATTCAC 660
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       1899 CCGGAGGACAGGTTACTTCAGAAAGTGAGAGAAAGTAATTTGGACAAATAAAACATTCAC 1958

Qy        661 GATTTTGT 668
              ||||||||
Db       1959 GATTTTGT 1966
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Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gyan Chandra whose telephone number is (571) 272-2922. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gyan Chandra
Art Unit 1646
18 June 2007
Fax: 571-273-2922

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